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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,244	10/30/2001	Guillermo J. Tearney	00786-443001 / MGH 1542.1	4538
26161	7590	06/07/2004	EXAMINER SHAW, SHAWNA JEANNINE	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ART UNIT 3737	PAPER NUMBER 9

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,244

Applicant(s)

TEARNEY ET AL.

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/30/01, 3/11/02, 5/10/02, 5/3/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 29-38 and 44-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 27, 28 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3, 4.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, Species A in Paper No. 8 is acknowledged.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

3. Claim 28 is objected to because of the following informalities: It does not appear that claim 28 corresponds to the elected species. Appropriate correction is required.

Claim Interpretation

It is noted on page 10 of the specification that time intervals "sufficient to detect microscopic Brownian motion" for atherosclerotic plaque are about "1-200 ms."

On page 11 the examiner notes that the PR interval of the diastole of a heartbeat lasts for about "0.12-0.2 seconds, providing sufficient time to detect Brownian motion."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 12, 14-16, 21-23, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon et al.

Regarding claims 1-6, 12, 14-16, 21-23, 25, 27 and 28, Vachon et al. teaches a method for analyzing stress and strain in atherosclerotic plaque including illuminating artery regions with coherent or partially coherent light (e.g., infrared light, col. 5 lines 38-44; also incorporating by reference its parent application disclosing functional theory of laser speckle interferometry), receiving reflected light to form a series of speckle patterns (col. 2 lines 27-58), and analyzing changes in the speckle patterns (col. 3 lines 3-14) at time intervals "sufficient" (i.e., in real time, during diastole) to measure changes "caused by" microscopic motion of objects within tissue (inherently including Brownian and cellular motion). Vachon et al. further teaches digitizing and quantitatively correlating the speckle patterns to a reference pattern (col. 2 lines 39-45, claim 6). Vachon et al. additionally discloses video camera (18) which obtains real time speckle data. See also figures 1 and 3 and claims 1-5.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7-11, 13, 18-20, 24, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon et al. in view of Kirkpatrick et al. "Laser speckle microstrain measurement in vascular tissue" of record or Moreno et al.

Regarding claims 7-11, 13, 18-20, 24, 39 and 40, Vachon et al. does not explicitly address invasively obtaining near field speckle data, however does recognize the difficulty in determining the status of hard and soft plaques using externally obtained speckle data (col. 3 lines 57-59). Kirkpatrick et al. and Moreno et al. likewise point out that external imaging techniques (e.g., angiograms, radiological imaging, ultrasound, etc.) are incapable of detecting the mechanical and chemical properties of intravascular plaques and for that reason use direct (i.e., intravascular) laser speckle/interferometric data (via e.g., catheter) to effect earlier detection of structural changes pertaining to atherosclerosis and thereby more accurately determine appropriate courses of action. See Kirkpatrick et al. pages 121, 128 and Moreno et al. ¶¶ 0002, 0004, 0009, 0014 and 0044. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to directly obtain optical speckle/interferometric data with (e.g., a catheter) for atherosclerotic plaque analysis as taught by Kirkpatrick et al. or Moreno et al. in the invention as taught by Vachon et al. to more accurately assess the status of

the intravascular plaques and determine appropriate courses of action thereby reducing procedure complication rates.

6. Claims 17 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon et al. in view of Kirkpatrick et al. "Laser speckle microstrain measurement in vascular tissue" of record or Moreno et al. and further in view of Boas et al. "Diffusing temporal light correlation for burn diagnosis" of record.

Regarding claims 17 and 41-43, Vachon, Kirkpatrick and Moreno differ from the claimed invention in that calculation of the decorrelation rate and comparison to a mathematical simulation model are not addressed explicitly. Boas et al. provides the general teaching of comparing optical tissue properties (taking into account the decorrelation rate) to mathematical simulation models such as Monte Carlo and diffusion theory to more easily and accurately predict and derive tissue structure data on a microscopic level (p. 468-472 and 475). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to compare the optical speckle data of Vachon et al. in view of Kirkpatrick or Moreno with mathematical simulation data as taught by Boas et al. to verify results and to derive more accurate tissue structure data on a smaller scale.

Allowable Subject Matter

7. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
5/27/04